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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,590	05/26/2005	Shojiro Matsuda	10873.1686USWO	9228

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EXAMINER	
CHRISS, JENNIFER A	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,590	MATSUDA ET AL.	
	Examiner	Art Unit	
	JENNIFER A. CHRISS	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 11-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10/2007 07/01/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Applicant's Amendments and Accompanying Remarks, filed December 27, 2007, have been entered and have been carefully considered. Claim 1 is amended, claims 29 - 32 are added, claims 6 - 10 are cancelled and claims 1 - 5 and 11 - 32 are pending. In view of Applicant's amendment to claim 1 requiring that the reinforcing material is a "warp knitted fabric in a form of a mesh with diamond-shaped pores or a mesh with hexagon pores and a unit of stitches of the warp knitted fabric has a vertical length of 0.5 to 8 mm and a horizontal length of 0.5 to 8 mm", the Examiner withdraws all previously set forth rejections as detailed in the Office Action dated July 27, 2007. The invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 – 5, 11 – 13, 15, 25 – 26, 28 and 30 – 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Browning (WO 02/078568 A1).

Browning is directed to a surgical implant (Title).

As to claims 1 – 4 and 30 - 31, Browning teaches a mesh that is coated or encapsulated with an absorbable coating (page 12, lines 7 – 11). Browning teaches that the absorbable material may comprise a soluble hydrogel such as gelatin (page 13, lines 6 – 8). Browning teaches that the mesh comprises bicomponent fibers comprising a nonabsorbable core and a shorter lasting absorbable surface material such as polylactic acid or polyglycolic acid (page 14, lines 28 - 31). The mesh can comprise a warp knit diamond or hexagon net (page 9, lines 11 - 14) where strand spacing is between 1 - 10 mm (page 7, lines 18 - 20), which is equated to Applicant's "vertical length" and "horizontal length". The Examiner equates the warp knit mesh to Applicant's "reinforcing material" and the gelatin coating or encapsulating material to Applicant's "gelatin film".

As to claim 5, the Figures show that the surgical implant can be in sheet form.

As to claim 11, Browning teaches applying a heat treatment to the warp mesh knit to reduce fraying of the filaments (page 37, lines 1 – 6).

As to claim 12, Browning teaches that the warp knit mesh has a density of less than 50 gsm (page 8, lines 1 – 12), which significantly overlaps with Applicant's claimed range

As to claim 13, Browning teaches that the mesh comprises strands that are approximately 150 - 600 microns in diameters (page 34, lines 12 - 15), therefore, the mesh will be at least 150 - 600 microns in thickness.

As to claim 15, Browning teaches that the mesh comprises bicomponent fibers

comprising a nonabsorbable core and a shorter lasting absorbable surface material such as polylactic acid or polyglycolic acid (page 14, lines 28 - 31).

As to claim 25, Browning teaches that the surgical implant is capable of being absorbed by the body in a period less than 48 hours (page 15, lines 6 - 9).

As to claim 26, Browning teaches that the absorbable coating may have a thickness around 1 – 2 mm (1000 – 2000 micrometers) (page 38, lines 4 - 14).

As to claim 28, Browning teaches the claimed invention above. It should be noted that the recitation of "antiadhesive material" is not given patentable weight at this time since the prior art meets the structural and/or chemical limitations set forth and there is nothing on record to evidence that the prior art product could not function in the desired capacity or that there is some additional implied structure associated with the term. The burden is shifted upon the Applicant to evidence the contrary.

Claim Rejections - 35 USC § 102/103

5. Claims 14 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Browning (WO 02/078568 A1).

Browning teaches the claimed invention above but fails to teach that the yarn threading tension is in a range of 0.3 - 200 N as required by claim 14 and neither rupture nor exposure of the reinforcing material occurs when the tension is less than 1 N as required by claim 32. It is reasonable to presume that the above properties are inherent to Browning. Support for said presumption is found in the use of like materials (i.e. a warp knitted mesh having diamond or hexagonal shaped pores made of a

biodegradable polymer having the same unit of stitches coated with a gelatin) which would result in the claimed properties. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would obviously have been present once the Browning product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

Claim Rejections - 35 USC § 103

6. Claims 17 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Matsuda (EP 1,022,031 A1).

Browning teaches the claimed invention above but fail to teach that the gelatin is cross-linked and that the gelatin is subjected to a hydrophilicity imparting treatment selected from the group consisting of a plasma treatment, glow discharge treatment, corona discharge treatment, ozone treatment, graft treatment, coating, chemical treatment, and ultraviolet treatment.

Matsuda is directed to a suturable adhesion-preventing membrane with high suture strength, good biocompatibility, decomposition and absorption in a living body (Abstract). The membrane is composed of at least one non-woven fabric layer and a coating of gelatin on the surface or surfaces of the membrane (Abstract). Matsuda notes that cross-linking allows the membrane to remain in a living body while maintaining a necessary membrane strength until reconstruction of an injured surface and tissue regeneration are completed (page 6, [0043]). Matsuda teaches that the crosslinking is provided by chemical crosslinking, ultraviolet ray, thermal dehydration and other

methods (page 6, [0044]). It is not seen that the specific process steps set forth in claims distinguish the presently claimed article from the prior art articles as the references expressly suggest crosslinking the gels used therein. The courts have held that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is .unpatentable even though the prior product was made by a different process." *In re Thorpe,* 777 F.2d 695,698,227 USPQ 964,-966 (Fed. Cir. 1985).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to cross-link the gel of Browning or provide a hydrophilicity imparting treatment as suggested by Matsuda motivated by the desire to create a surgical implant which is capable of remaining in the body while maintaining the necessary strength until reconstruction of the injured surface and/or tissue regeneration are completed.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Jurgens (US 5854381).

Browning teaches the claimed invention above but fail to teach the use of 85:15 – 40:60 lactide:caprolactone copolymer.

As shown by Jurgens to was known to provide a bioabsorbable polymer comprising lactide and caprolactone in a molar ration between 90:10 and 70:30.

It would have been obvious to a person having ordinary skill in the art to have

provided such a bioabsorbable material to the material of Browning in order to provide a polymer that is suitable for preventing surgical adhesions.

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1) in view of Consolazio (US 4,374,063).

Browning teach the claimed invention above but fail to indicate the specific amount of endotoxin present in the gel.

Consolazio teach that the pharmaceutical field requires gels that are free from endotoxins.

It would have been obvious to a person having ordinary skill in the art to have provided an endotoxin free gel since endotoxins are bad for the body.

9. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning (WO 02/078568 A1).

Browning teach the claimed invention but fail to disclose that the warp knitted fabric comprises a multifilament yarn having a thickness of 30 – 200 denier as required by claim 29. It should be noted that the linear density is a result effective variable. Browning indicates that the filaments of the mesh have a diameter of 0.02 to 0.15 mm which is directly related to denier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the knitted mesh of Browning with a yarn denier ranging from 30 to 200 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one

would have been motivated to optimize the yarn denier of Browning based on the desired strength and flexibility of the surgical implant.

Response to Arguments

10. Applicant's arguments with respect to claims 1 – 5 and 11 – 32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is

(571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. C./
Examiner, Art Unit 1794

/Ula C Ruddock/
Primary Examiner, Art Unit 1794